REMARKS

Reconsideration and withdrawal of the objections and rejections of the claims, in view of the amendments and remarks herein, is respectfully requested. Claims 20, 24 and 34 are amended. Claims 1-45 are pending in this application.

In response to the finality of the Restriction Requirement, Applicant reserves the right to petition the Commissioner to review the Restriction Requirement, and in particular, the requirement to elect a specific nucleotide sequence in the absence of a species election.

The specification is amended at page 23 to insert sequence identifier numbers. With respect to sequence identifier numbers in Figure 5, the Examiner is requested to refer to the Preliminary Amendment filed on February 10, 2004, in which the Brief Description of Figure 5 was amended to insert sequence identifier numbers.

Claims 17, 24 and 34 were objected to because the claims are drawn to non-elected subject matter. As Applicant reserves the right to have the Commissioner review the appropriateness of the Restriction Requirement, claims 17, 24 and 34 have not been amended to cancel non-elected subject matter.

Claims 20 and 32 were objected to for the term "PEST". Although "PEST" is a term of art, see, e.g., Leclerc et al. (Biotechniques, 29:590 (2001), a reference cited against the claims under 35 U.S.C. § 102(b) and § 103(a)), claim 20 is amended to address this objection.

Claims 24 and 34 were objected to for the term "CL1". The amendments to claims 24 and 34 obviate this objection.

Claims 30-31 were objected to for the word "of" after "half-life" in line 2. It is Applicant's position that "of" in "half-life of expression" is proper, as it conveys that the half-life is that of expression.

Accordingly, withdrawal of the objections to claims 17, 20, 24, 30-32, and 34 is respectfully requested.

The 35 U.S.C. § 112, Second Paragraph, Rejections

Claim 3-7, 15-17, 32-37, and 41-44 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase "codons which are preferentially employed in a select host cell." This rejection is respectfully traversed.

It is Applicant's position that codons which are preferred in a particular host cell are known to the art (see, e.g., Wada et al., Nucl. Acids Res., 18:2367 (1990), cited on page 26 of the specification). Therefore, the metes and bounds of the phrase "codons which are preferentially employed in a select host cell" in the claims is clear.

Claims 4-7, 10, 15-17, 32-37, and 41-44 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for reciting a nucleic acid sequence which is "optimized" for expression. This rejection is respectfully traversed.

It is Applicant's position that one of skill in the art is well aware of sequences that can optimize expression. Even if, assuming for the sake of argument, the metes and bounds of "optimized sequences" is not readily understood by one of skill in the art, Applicant's specification discloses exemplary optimization of various sequences, e.g., introduction of Kozak sequences, introduction of introns, and replacement of codons with codons preferred in a particular host (see page 5 of the specification). Hence, the metes and bounds of "optimized sequences" in the claims are clear.

Claim 17 was rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for reciting "substantially the same activity." This rejection is respectfully traversed.

The Examiner is requested to consider page 6 of the specification, which discloses that the activity of a fragment of a fusion polypeptide has "substantially the same activity" (at least 70% the activity) of a corresponding full-length fusion polypeptide. Accordingly, claim 17 is clear.

Claims 20 and 32 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for "PEST." As mentioned above, "PEST" is a term of art and so would be understood by one of skill in the art. Nevertheless, to advance the application, claim 20 is amended.

Claim 24 and 34 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for reciting " CL1, CL2, CL6, CL9, CL10, CL11, CL12, CL15, CL16, or SL17." Although it is Applicant's position that those terms, in view of Applicant's specification, e.g., see

the citation for Gilon et al. (EMBO J., 17:2759 (1998)) at page 23 of the specification, would be understood by the art, claims 24 and 34 are amended.

Claim 30-31 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for reciting "half-life of expression." This rejection is respectfully traversed.

The specification discloses that proteins and RNA have a half-life (pages 2-3 of the specification) and that the half-life of a gene product can be altered by attaching a plurality of destabilization sequences (pages 4-6 of the specification), e.g., one or more protein destabilization sequences, one or more RNA destabilization sequences, or a combination of protein destabilization sequences and RNA destabilization sequences, to a nucleic acid for the gene product. Thus, it is clear that certain sequences can alter the half-life of expression of a linked nucleic acid sequence.

Therefore, withdrawal of the 35 U.S.C. § 112(2) rejections is respectfully requested.

The 35 U.S.C. § 112, First Paragraph, Rejections

Claims 1-11, 15-16, 18-20, 24-25, 30-32, 34-37, and 41-44 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. In particular, the Examiner asserts that the specification only describes a polynucleotide having the nucleic acid sequence of SEQ ID NO:72, which encodes a fusion polypeptide having a specific firefly luciferase, a specific PEST sequence, a specific CL1 sequence, and a specific UTR sequence. Claims 1-11, 15-16, 18-20, 24-25, 30-32, 34-37, and 41-44 were also rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a polynucleotide having the nucleic acid sequence of SEQ ID NO:72 and vectors and host cells having the polynucleotide, allegedly does not reasonably provide enablement for a polynucleotide encoding a fusion polypeptide having any reporter protein and any protein destabilizing and/or mRNA destabilizing sequences having any structure, including any or all variants, mutants and recombinants thereof of said sequences. These rejections are respectfully traversed.

Reporter proteins (e.g., see Andreatta et al., Biotechniques, 30:656 (2001), and Leclerc et al., Biotechniques, 29:590 (2001)), protein degradation signals (see, e.g., Leclerc et al., Biotechniques, 29:590 (2001), Gilon et al., EMBO J., 17:2759 (1998), King et al., Mol. Biol.

Cell, 7:1343 (1996) and Rechsteiner et al., Sem. Cell. Biol., 1:433 (1990)), and UTRs with RNA destabilization sequences (e.g., see Fan et al., Genes and Devel., 11:2557 (1997), Balmer et al., Mol. Cell. Biol., 21:2070 (2001), and Belanger et al., Soc. Neurosci. Abs., 26:411.7 (2000)) (all of record) are known to the art. Applicant need not describe what is known to the art.

Moreover, contrary to the Examiner's assertion, the specification exemplifies three different firefly luciferase sequences, two different click beetle luciferase sequences, a *Renilla* luciferase sequence, a green fluorescent protein sequence, protein destabilization sequences (see pages 5 and page 23 which disclose numerous sources for protein destabilization sequences), and RNA destabilization sequences (see page 6 of the specification).

Further, Applicant prepared and tested numerous constructs falling within the scope of the claims (see the Example).

Therefore, the specification is clearly in compliance with 35 U.S.C. § 112(1).

The 35 U.S.C. § 102(b) Rejection

Claims 1-11, 15-16, 18-20, 25, 32, 35-37, and 41-44 were rejected under 35 U.S.C. § 102(b) as being anticipated by Leclerc et al. (Biotechniques, 29:590 (2001)). This rejection is respectfully traversed.

Leclerc et al. prepared a construct in which a coding sequence for a firefly luciferase was linked to a murine ornithine decarboxylase (mODC) coding sequence that includes a PEST sequence found near the C-terminal of mODC. It is disclosed that the PEST sequence in mODC corresponds to residues 423-450, and that residues 423-461 of mODC (modified by an amino acid substitution at two positions), i.e., the C-terminal residues of mODC, were fused to firefly luciferase sequences (see Figure 1).

Leclerc et al. do not teach or suggest the use of combinations of destabilization sequences, or an optimized luciferase sequence with at least one destabilization sequence.

Accordingly, withdrawal of the 35 U.S.C. § 102(b) rejection is respectfully requested.

The 35 U.S.C. § 103(a) Rejection

Claims 17 and 30-31 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Leclerc et al. as applied to claims 1-11, 15-16, 18-20, 25, 32, 35-37, and 41-44 above, and

further in view of Gilon et al. (EMBO J., 17:2759 (1998)). This rejection is respectfully traversed.

Gilon et al. do not provide what is missing in Leclerc et al., as Gilon et al. do not teach or suggest the use of combinations of destabilization sequences or an optimized luciferase sequence with at least one destabilization sequence.

Therefore, withdrawal of the 35 U.S.C. § 103(a) rejection is respectfully requested.

CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney at (612) 373-6959 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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Date September 28, 2006 By _____
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Reg. No. 39,665

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Mail Stop Amendment, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 28th day of September 2006.

Dawn M. Fowle _____ Dawn M. Fowle _____

Name Signature